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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/732,890

12/10/2003

James R. Lisk JR.

5N03.1-011

6906

23506

7590

12/29/2009

GARDNER GROFF GREENWALD & VILLANUEVA. PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

12/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/732,890	Applicant(s) LISK ET AL.	
	Examiner MICHAEL G. MENDOZA	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-25,31,32,34-38 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-25,31,32,34-38 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/30/2009 have been fully considered but they are not persuasive.
2. The applicant argues that the only types of blades that are known to have been used for forming a corneal flap are extremely sharp and expensive precision metal blades. The applicant also argues that the use of a polymer blade would be novel. The examiner disagrees. Pallikaris et al. teaches a blunt blade for peeling back the corneal epithelium. Pallikaris et al. does not teach the use of a "extremely sharp and expensive precision metal blade". The secondary teaching reference to Foggia et al. teaches that it is known to use a polymer blade as an alternate to a metal blade. The examiner would like to remind the applicant that Foggia et al. is a teaching reference for the use of a polymer as opposed to a metal for a blade. The examiner is not relying on Foggia et al. for the teaching of a sharp blade or for a blade for the cutting of a finger.
3. The applicant argues that Foggia et al. is not pertinent art. The examiner disagrees. Foggia et al. is within the art of cutter/blades.
4. The applicant argues that Samuels et al. is not pertinent art. The examiner disagrees. Samuels et al. is within the art of cutters/blades.
5. The applicant argues that the references do not teach disposing of the separator after a single use. It is well known in the art of surgery to dispose of blades after a single use to reduce contamination.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3-8, 13-20, 25, and 31, 32, 34-38, and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris et al. 7004953 in view of Foggia et al 5782852.

8. As to claims 1, 14, 31, 32, Pallikaris et al. teach a surgical device comprising: a positioning ring; and a separator assembly including a separator having a blunt separating edge; wherein the radius of curvature of the separating edge of the separator is between 5 micron and about 100 microns, or 10 microns and about 30 microns, or 15 microns and 25 microns (col. 6, lines 22-29); wherein the separating edge is flat, wherein the separating edge is rounded, wherein the separating edge includes an angled point (see fig. 23).

9. Pallikaris et al. teaches that the blade can be manufactured from a material that is strong enough to push epithelium without breaking. It should be noted that Pallikaris fails to teach the preferred materials and their properties. It is known in the art to use a polymeric blade in place of a metal blade in the surgical art as evidenced by Foggia et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymeric blade as taught by Foggia et al. as a mechanical expedient to a metal blade (see entire reference).

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10. As to claims 3-8, 15-20, 25, 34 Pallikaris/Foggia teaches the claimed invention except for the properties of the polymeric material. Foggia et al. teaches the use of polymers (col. 5, lines 21-25). These polymers are also recited in the claim limitations and can be made with the same recited properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymer having the recited structural properties, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. As to claim 36 and 37, Pallikaris et al. teaches a metal blade. It should be noted that Pallikaris et al. fails to teach a polymer coating on the edge of the blade. However, it is well known in the art of blades to coat the edge of a blade with a polymer, e.g., Teflon, for hardening, anticorrosive properties, or as a lubricative layer for the metal blade. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a polymer coating to the edge of the blade of Pallikaris et al. to enhance the properties of the blade.

12. As to claim 41, Pallikaris/Foggia teaches the claimed invention except for the leading edge portion size range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range limitations, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

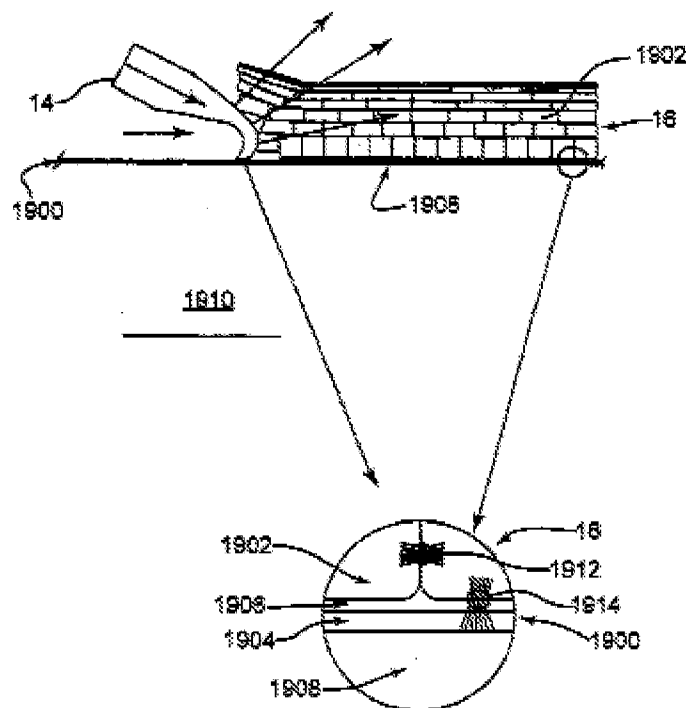


FIG. 19

13. Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Samuels et al. 6247389.

14. Pallikaris/Foggia teaches the surgical device as claimed in claim 1.

Pallikaris/Foggia teaches the use of a non-brittle polymer blade. Samuels et al. teaches the use of fillers (glass fiber and carbon fiber) for reinforcing polymer blades. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the fillers in view of Samuels et al. to reinforce the polymer blades to make them less brittle.

15. Claim 10, 12, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Feingold 6083236.

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16. Pallikaris/Foggia teaches the surgical device as claimed in claim 1. It should be noted that Pallikaris/Foggia fails to teach wherein the polymeric edge comprises a transparent material. However, Feingold teaches the use of a transparent blade (col. 6, lines 24-25). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the polymeric blade of Pallikaris/Foggia transparent for the best visibility during the process of separation.

17. As to claims 12 and 24, the above combination teaches the device of claim 10. It should be noted that the combination fails to specifically teach the limitation of the transparent material comprises a tinting agent. However, the combination teaches that the transparent material need not transmit all light (light transmission greater than 75 percent). If the transparent material does not transmit all light, there would be some type of tint blocking the rest of the light transmission. Therefore, the above combination does teach some type of tinting agent.

18. Claims 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Scwemberger et al. 5569292.

19. As to claims 11 and 23, Pallikaris/Foggia/Feingold teaches the device as claimed in claim 10 and 22. It should be noted that the above combination fails to disclose a light transmission greater than about 50, and a haze factor less the 25 percent.

However, Scwemberger teaches the use of a surgical blade of a plastics material with similar limitations that does not obstruct the visual field during operation (col. 7, lines 14-17). Therefore, it would have been obvious to one having ordinary skill in the art at the

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time the invention was made to use the light transmission and haze factor for viewing in view of Scwemberger.

Conclusion

20. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734